UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/170,344	03/30/1	KAST	D4511STFM

EXAMINER
MINNIFIELD,N

18N1/0823

COOPER & DUNHAM
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

ART UNIT	PAPER NUMBER
1813	13

DATE MAILED: 08/23/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on 4-07-95 5-15-95 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1-2, 4-22, 24 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☒ Claims 3 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-2, 4-22, 24 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Part III DETAILED ACTION

15. Applicants' amendments filed January 4, 1994 and July 18, 1994 are acknowledged and have been entered. Claim 23 has been cancelled. Claims 4, 5, 6, 8, 10, 12, and 14-22 have been amended. Claims 1-22 and 24 are now pending in the present application.

16. The information disclosure statement filed January 4, 1994 fails to comply with 37 CFR § 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered as to the merits.

Claim Rejections - 35 USC § 112

17. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure. The specification is not enabled for the

broad scope of the claimed invention. For example, claim 1 refers to a peptide comprising an amino acid sequence from a protein of HPV, which HPV protein includes HPV5, HPV1a, HPV16, HPV18, HPV11, HPV33, HPV8, or HPV6b and any peptide from these proteins from HPV. The specification has not taught a person of ordinary skill in the art how to prepare a peptide from any of the listed HPV proteins wherein the peptide binds to any human MHC Class I molecule. The disclosure is enabled for nanopeptide sequences from the E6 or E7 genes of HPV16 or HPV18, and MHC Class I molecules as specifically taught in the specification. The specification is not commensurate in scope with the claims of the invention. Further, the specification has not provided sufficient evidence of a method of prophylactic or therapeutic treatment of a human with cervical carcinoma or other HPV related diseases by administering a peptide from HPV proteins in a pharmaceutical composition. Matlashewski et al. discloses that HPV18 proteins (E6 gene) maybe diagnostically useful since the proteins have been identified in specific human cancers, however the methods as claimed in this invention are not known in the art. Accordingly, amendment of the claims to what is supported in the specification or filing of evidence in the form of a Rule 132 declaration providing factual evidence supporting the broad range claims is suggested.

A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which it pertains to make and use the invention as of its filing date, In re Glass, 181 USPQ 31; 492 F2.d 1228 (CCPA 1974). While the prior art setting may be mentioned in general terms, the essential novelty, the essence of the invention, must be described in such details, including proportions and techniques where necessary, as to enable those persons skilled in the art to make and utilize the invention.

Specific operative embodiments or examples of the invention must be set forth. Examples and description should be of sufficient scope as to justify the scope of the claims. Where the constitution and formula of a compound is stated only as probability and speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula. A disclosure involving a new chemical compound or composition must teach persons skilled in the art how to make the compound. Incomplete teachings may not be completed by reference to subsequently filed applications.

Please note that when applicant predicates utility for the claimed compounds on allegations which are or border on the incredible in light of contemporary knowledge of the particular art, those allegations must be substantiated by acceptable evidence, see In re Ferens (CCPA) 163 USPQ 609. The amount of evidence which is acceptable and the character of such evidence required will obviously vary depending on the facts of each case, but the degree of certainty regarding the truth of the ultimate fact to be proven remains constant, see In re Gazave, 54 CCPA 1524, 379 F.2d 973, 154 USPQ 92 (1967). Evidence submitted to establish usefulness must be such as would be clear and convincing to one of ordinary skill in the particular art. In re Irons, 52 CCPA 938, 340 F.2d 974, 144 USPQ 351 (1965). Applying those principles set forth above upon which the assertion of usefulness of the instant compounds is based, i.e. the alleged usefulness of a method of prophylactic or therapeutic treatment of a human with cervical carcinoma or other HPV related diseases by administering a peptide from HPV proteins in a pharmaceutical composition, there is seen insufficient evidence.

The instant specification invites the skilled artisan to experiment. The factor which must be considered in determining undue experimentation are set forth in Ex parte Forman 230 USPQ

546. The factors include 1) quantity of experimentation necessary, 2) the amount of guidance presented, 3) the presence or absence of working examples, 4) the nature of the invention, 5) the state of the prior art, 6) the predictability of the art and the 7) breath of the claims. With regard to factors three and six, it is noted that there are no working examples of the in vivo efficacy of the active ingredients in a method of prophylactic or therapeutic treatment of a human with cervical carcinoma or other HPV related diseases by administering a peptide from HPV proteins in a pharmaceutical composition, or peptides from any HPV that bind to MHC Class I molecules. Such is not seen as sufficient to support the breath of the claims, wherein the scope of the claims encompasses how to prepare a peptide from any of the listed HPV proteins (or any other HPV protein) wherein the peptide binds to any human MHC Class I molecule. It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves., see In re Gardner et al. 166 USPQ 138 (CCPA 1970).

18. Claims 1-22 and 24 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

19. Claims 1-22 and 24 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited the HPV16 and HPV18 peptides taught in the specification. See M.P.E.P. §§ 706.03(n) and 706.03(z).

20. Claims 16-21 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point

out and distinctly claim the subject matter which applicant regards as the invention. Claims 16-21 are vague and indefinite in the use of the phrase "effective amount", because the claims fail to state the function which is to be achieved.

Claim Rejections - 35 USC § 102 and 103

21. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

22. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

23. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

24. Claims 1-22, and 24 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Schoolnik et al..

The claimed invention is drawn to a peptide from a HPV protein wherein the peptide binds to a MHC Class I molecule, and a method of prophylactic or therapeutic treatment of a human with cervical carcinoma or other HPV related diseases by administering a peptide from HPV proteins in a pharmaceutical composition.

Schoolnik et al. discloses synthetic peptides from HPV that are useful in the diagnosis and therapy of conditions associated with HPV infection (abstract; p. 9, l. 10-18; claims). Schoolnik et al. teaches the preparation of peptides from HPV16 (E6 and E7) or other HPV proteins useful to raise antibodies for diagnostic, protective (i.e. prophylactic), and therapeutic purposes and vaccines, as well as various mode of administration (p. 3, l. 1-39; p. 5, l. 28-50; p. 4, l. 27 to p. 5, l. 24; p. 7, l. 47 to p. 8, l. 8). The teachings of Schoolnik et al. anticipates the claimed invention by disclosing a peptide from a HPV protein wherein the peptide binds to a MHC Class I molecule, and a method of prophylactic or therapeutic treatment of a human with

cervical carcinoma or other HPV related diseases by administering a peptide from HPV proteins in a pharmaceutical composition. The compositions and methods disclosed in Schoolnik et al. are believed to inherently possess properties which anticipates the claimed invention or if they are not the same the composition and methods, the HPV peptides (and compositions) and methods of treatment as disclosed by Schoolnik et al. would none the less render the claims obvious because it possesses the components necessary to prepare a peptide from HPV and methods of treatment as claimed in the instant application. Binding of MHC Class I molecules via T-cell activation is an inherent part of the process of generating an immunogenic response in a mammal. Since the Office does not have the facilities for examining and comparing applicants' method for preparation of a HPV peptide and methods of treatment of the prior art, the burden is on applicant to show a novel or unobvious differences between the claimed product and the product of the prior art (i.e., that the peptide from a HPV protein wherein the peptide binds to a MHC Class I molecule, and a method of prophylactic or therapeutic treatment of a human with cervical carcinoma or other HPV related diseases by administering a peptide from HPV proteins in a pharmaceutical composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition and methods of preparation). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

25. No claims are allowed.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is (703) 305-3394.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

N. M. Minnifield

Octeber 3, 1994

CHRISTINE M. NUCKER
SUPERVISORY PATENT EXAMINER
GROUP 180